

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
8 August 2002 (08.08.2002)

PCT

(10) International Publication Number
WO 02/060330 A1

(51) International Patent Classification⁷: A61B 17/58

(21) International Application Number: PCT/US02/02703

(22) International Filing Date: 29 January 2002 (29.01.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/264,943 29 January 2001 (29.01.2001) US

(71) Applicant and

(72) Inventor: RITLAND, Stephen [US/US]; 1150 N. San Francisco Street, Flagstaff, AZ 86001 (US).

(74) Agents: YASKANIN, Mark, L. et al.; Sheridan Ross P.C.,
1560 Broadway, Suite 1200, Denver, CO 80202-5141 (US). Published:

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

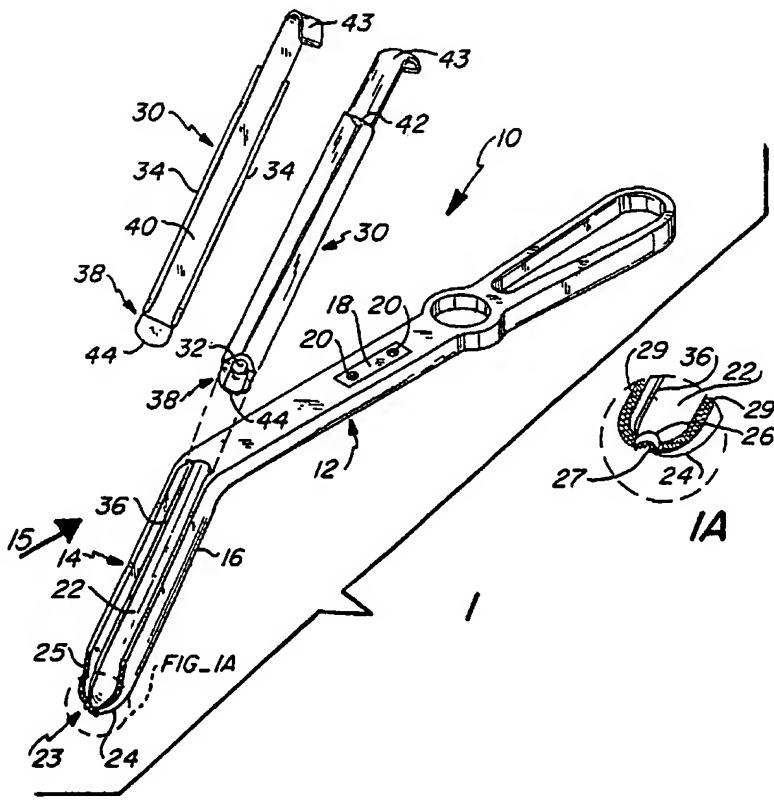
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: RETRACTOR AND METHOD FOR SPINAL PEDICLE SCREW PLACEMENT



WO 02/060330 A1



(57) Abstract: To avoid traditional muscle dissection required in the placement of a screw for a pedicle screw fixation, a retractor (10) is provided having a guide (14) of an appropriate length to provide access from the skin surface to the dorsal aspect of the vertebra over the pedicle. The retractor (10) has a handle (12) to provide appropriate holding leverage and to maintain the guide (14) so as to stabilize the guide (14) against the lateral aspects of the facet with the paraspinous musculature. The retractor (10) has a channel (22) of an appropriate size to accommodate a variety of tools, including a drill bit or a tap (33). The channel (22) also provides a pathway for a probe (30) or feeler to inspect the placement of the screw.

WU 0-000350 A1

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

RETRACTOR AND METHOD FOR SPINAL PEDICLE SCREW PLACEMENT

FIELD OF THE INVENTION

The present invention is directed to a novel retractor and a method using such
5 retractor for placing spinal pedicle screws.

SUMMARY OF THE INVENTION

Pedicle screw fixation has become an important part of stabilizing the spine to assist
in arthrodesis. Traditionally a significant amount of muscle dissection has been required to
10 prepare for screw placement. Recently, various approaches have been developed to minimize
unnecessary disturbance of paraspinous structures while still accomplishing satisfactory
fixation of the spine and the concomitant grafting necessary to achieve arthrodesis.

The retractor of the present invention eases intermuscular placement of pedicle
screws by providing a minimally invasive approach, and specifically lends itself to image
15 guided applications. The characteristics of the retractor are described below with
accompanying figures to illustrate the features.

The retractor's guide channel is of an appropriate length to provide access from the
skin surface to the dorsal aspect of the vertebra over the pedicle. The handle of the retractor
is attached to provide appropriate holding leverage to maintain the position of the retractor
20 and to stabilize its guide portion against the lateral aspect of the facet with the paraspinous
musculature.

An elongated insert may be placed within the guide channel of the retractor. The
insert provides a working channel or hollow bore of an appropriate size to accommodate
various instruments. For example, the working channel may receive an awl or perforator for
25 the bony cortex, a drill for the pedicle if desired, or a tap for the pedicle and body of the
vertebra. The working channel also provides a pathway for a probe or feeler to inspect the
placement of the screw. Additionally, the insert may be configured to allow for guided
instruments to confirm position of the screw placement. Moreover, attachment of a tracker
30 to the retractor, the insert, or to instruments used through the insert allows coupling of the
surgical procedure with an image guided system.

The retractor is configured such that removal of the insert from the guide channel of
the retractor provides a protected working channel for placement of the pedicle screw. The
tip of the retractor may be textured and obliquely cut to help maintain position of the retractor

against the lateral aspect of the facet. The guide channel is preferably open on one side to allow removal of the retractor after placement of the screw. The channel is of sufficient length to maintain muscle retraction necessary for screw placement.

- 5 The shape of the distal end of the retractor aids easy placement of the retractor with minimal muscle separation, thus helping to displace soft tissues while placing the retractor and minimizing the tendency of the retractor to catch on soft tissue during entry. Preferably, there are projections and a textured distal surface to help maintain position against the bone and to avoid displacement while working through the retractor. The cutout, preferably semi-circular or curved, at the distal end is of an appropriate size to allow use of a tap and subsequent placement of a pedicle screw.

10

BRIEF DESCRIPTION OF THE DRAWINGS

- Fig. 1 is a perspective view of one embodiment of the retractor of the present invention, and front and rear views of an embodiment of the insert for the retractor;

15 Fig. 1a is an enlarged view of the distal end of the retractor;

Fig. 2 is a front elevation view of the retractor of Fig. 1, taken along arrow 15, of one embodiment of the insert for the retractor adapted for use with a surgical tap, and a surgical tap;

20 Fig. 3 is a vertical cross-sectional view of the retractor and an insert mounted within the retractor;

Fig. 4 is a horizontal cross-sectional view of the retractor taken along line 4-4 of Fig. 3 and an insert mounted within the retractor;

25 Fig. 5 is perspective view of the retractor of the present invention during use in a human spine wherein an insert is placed within the retractor and a tap is inserted through the insert;

Fig. 6 is another perspective view of the retractor, with the insert removed and the retractor being used as a guide for emplacement of a pedicle screw;

0 Fig. 7 is a perspective view of a further embodiment of the present invention having a recessed and curved distal tip at its guide portion; and

Fig. 8 is a perspective view of the retractor of the present invention fitted with an image tracker on the retractor's handle, shown in simulated application with the human spine.

DETAILED DESCRIPTION

With reference to Fig. 1, retractor 10 of the present invention is depicted in a perspective view. Retractor 10 preferably comprises two portions, a handle 12 and a guide portion 14. Handle 12 is attached to the proximal end of guide portion 14. Handle 12 may 5 be of various configurations to allow access to the surgical site while providing a means of gripping the retractor 10 such that sufficient leverage may be applied to maintain the desired orientation of retractor 10 at the surgical site. In a preferred embodiment, handle 12 is oriented at an angle of between about 90 and about 135 degrees from the guide portion 14. Handle 12 may include a slot 18 for interconnecting an attachment or a supplemental handle 10 using handle screws 20. Provision of slot 18 allows for various supplemental handle configurations to be used with retractor 10 to provide different holding leverages, as well as to provide interchangeable geometries that may be desired to overcome spatial constraints imposed by a specific patient's physical attributes. Alternately, an image tracker may be attached to slot 18 as discussed further below.

15 Guide portion 14 is used for access to the interior of the surgical site. Typically, an incision is made in the patient's skin and muscle. Subsequently, the guide portion 14 is inserted through the exterior portion of the incision to create and maintain access to the interior targeted body part, such as the patient's spine. As described below, specific features of guide portion 14 provide for improved access to the spine.

20 Guide portion 14 is preferably half-cylinder or U-shaped. More particularly, the rear surface 16 of guide portion 14 is preferably convex when viewing retractor 10 from the rear side of retractor 10. The U-shaped front of guide portion 14 includes a hollow region or guide channel 22. Guide channel 22 extends from the distal end 23 of guide portion 14 up to and including the upper-most or proximal end of guide portion 14. In this manner, guide 25 channel 22 may be used to guide surgical tools and implants from the exterior of the surgical site down to the interior-most portion of the surgical site by inserting surgical tools down through the guide channel.

25 The distal end 23 of guide portion 14 includes a rounded tip 24. In addition, the distal end 23 of guide portion 14 is shown as being truncated obliquely along the lower medial face 30 to more closely approximate the lateral aspect of the facet of the paraspinous musculature of the patient, and provide for improved medial positioning of the guide portion 14 for placement of a drill and/or tap into the bony structure of the patient. The rounded tip 24 may

further include a cutout or an opening 26 at its end. In a preferred embodiment shown in Fig. 1a, opening 26 is semicircular. One or more projections 27 may be provided around the end-most portion of opening 26 to aid in maintaining the position of the retractor 10 during use by stabilizing retractor 10 against the bony surface of the vertebrae. In addition, texturing 5 such as ridges and grooves or machined points may be placed on the medial surface 29 of the lower medial face 25 of guide portion 14 to further stabilize retractor 10 when in use.

Referring now also to Figs. 2 and 4, to aid in facilitating use of tools at the distal end of guide portion 14, an insert 30 may be placed within guide channel 22 to assist the surgeon in guiding and aligning tools along the desired orientation. In a preferred embodiment, insert 10 30 is generally triangular-shaped and has an aperture or hollow bore 32. Hollow bore 32 allows various tools to be guided down to the targeted area within the surgical site, such as tap 33.

15 Triangular-shaped insert 30 includes base edges 34. Base edges 34 of insert 30 cooperate with grooves 36 located within guide channel 22 to stabilize insert 30 within guide channel 22. Base edges 34 are simply side projections which mate with the grooves 36. Alternately, in lieu of base edges 34, insert 30 may include one or more discontinuous side projections (not shown). Similar to the base edges 34 of insert 30, these side projections could cooperate with a corresponding number of discontinuous grooves (not shown) located within guide channel 22 to aid in stabilizing insert 30 within guide channel 22.

20 Insert 30 includes a distal tip 38, a longitudinal shaft 40, a proximal end 42, and an optional handle 43. The distal tip 38 of insert 30 may be rounded, defining a perimeter edge 44. Perimeter edge 44 cooperates with the lower distal portion of groove 36 within guide channel 22 to further stabilize the distal tip 38 of insert 30, and to further prevent unnecessary entanglement with the patient's bodily tissues when inserting the insert 30 into the guide 25 channel 22.

Referring now to Figs. 3 and 4, the retractor 10 of the present invention is shown with 30 insert 30 received in the retractor 10. As described above, the base edges 34 of the triangular-shaped insert 30 mate with corresponding grooves 36 in the guide channel 22 of retractor 10. The distal tip 38 of insert 30 mates with the distal end 23 and rounded tip 24 of retractor guide portion 14 such that insert 30 does not extend beyond distal end 23. Figs. 30 3 and 4 also depict the hollow bore 32 through which a drill or tap 33 is inserted, thereby guiding the tap 33 to its targeted location.

With reference to Fig. 5, a tap 33 is shown inserted though the bore 32 of the insert 30, and the insert is placed in the guide channel 22 of retractor 10. Tap 33 is used to create an appropriate bore in the bone "B" for receipt of a medical device, such as a pedicle screw "S". Tap 33 may be sized in diameter to restrict passage of the tap 33 beyond a specified 5 length through insert 30. Specifically, tap 33 may contain a larger diameter section 50 which prevents passage of the tap 33 beyond the proximal opening 42 of insert 30.

With reference now to Fig. 6, once the tapping operation is complete, tap 33 and insert 30 may be removed from guide channel 22. Guide channel 22 remains in place and is then used to guide a medical device, in this case, a pedicle screw S. The retractor 10 thus 10 provides for proper alignment of the screw S. Further, the opening 26 in the distal end 23 of guide channel 22 is sized and shaped to accommodate the shank of screw S so that screw S may be properly aligned with the bore created by tap 33. Tool T, such as a medical screwdriver, is then used to finish installation of screw S by screwing screw S into bone B.

Referring now to Fig. 7, in a further embodiment, a retractor 10' without a rounded 15 tip is illustrated. As shown, the retractor has a recessed and curved distal tip 54. This embodiment offers the advantage of offering a U-shaped guide channel 22; however, a rounded tip is not present to interfere with visibility of the surgical site. The U-shaped guide channel 22 extends from the upper end of guide portion 14 down to the distal end 23 of the guide portion 14. As with the previous embodiment, distal end 23 of the guide portion 14 20 may be obliquely cut, with optional projections (not shown) formed at the end-most portion of the distal end 23. Additional texturing may also be provided along the medial surface of guide portion 14 to assist with stabilizing retractor 10' against the neighboring area of the surgical site.

Due to the frequently limited amount of exposure of the spine or interior surgical 25 area, the spinal implant procedures lend themselves to use of image guidance for surgery. Examples of such image guidance systems include the BrainLAB System and the Stealth System. As understood by those skilled in the art, these image guidance systems utilize a computer system with a monitor and two cameras that emit infrared signals, thereby determining the patient's position in the operating room as well as the position of the surgical 30 instruments in relation to the patient's spine. The image guidance systems use data from standard CT or MRI scans to build a three dimensional image of the patient's spine. This model is then electronically matched to the patient's anatomy during surgery, allowing the

surgeon, in effect, to see through tissue in order to accurately determine the placement of instruments or devices. During the operation, sensitive structures such as blood vessels and nerves, which the surgeon wants to avoid on the way to the anatomical target, can be visualized. In addition, during the operation the surgeon can follow the movements of his 5 or her instruments on the computer screen in real time.

Referring now to Fig. 8, retractor 10 is shown in one possible relationship with the human spine. The retractor 10 can be positioned at a desired location in relation to spinal processes and maintained in position with the projections 27 and texturing 28 which assist in anchoring the retractor on the patient. The insert 30 may then be used as a guide for 10 subsequent tapping, or like operations. The retractor 10 with insert 30 provides a working channel for tracked instruments. Attachment of a tracker 60 directly to insert 30, or alternately to the retractor handle 12 as shown in Fig. 8, allows a surgeon to guide the guide channel 22 of retractor 10, or hollow bore 32 of insert 30 directly, and thus avoid tracking the instruments themselves, such as a drill or tap 33.

15 All components of the invention described herein are manufactured of a material appropriate for surgical use. For example, the components can be made of stainless steel. However, it is to be understood that other types of materials may also be used, such as titanium or ceramics.

20 While various embodiments of the present invention have been described in detail, it is apparent that modifications and adaptations of those embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention.

What is claimed is:

1. A retractor especially adapted for placement of a pedicle screw within a patient, comprising:
 - a guide portion having a guide channel extending longitudinally therealong, said
 - 5 guide portion having a first and second end;
 - a handle connected angularly with respect to said first end of said guide portion; and
 - an insert configured to fit within said guide channel, said insert having an aperture extending lengthwise therethrough, said aperture having a diameter sized to accommodate a tool being inserted therethrough.
- 10 2. The device as claimed in claim 1, further comprising means for stabilizing said retractor against a lateral aspect of a facet of a paraspinous musculature of the patient.
3. The device as claimed in claim 1, wherein said second end of said guide portion includes at least one projection extending therefrom for assisting in anchoring the guide portion within the surgical area.
- 15 4. The device as claimed in claim 1, wherein said guide portion includes a medial face positioned adjacent said second end thereof, said medial face having a medial service formed with texturing thereon.
5. The device as claimed in claim 1, further comprising grooves formed within said guide channel for receiving at least one base edge of said insert.
- 20 6. The device as claimed in claim 1, further comprising an image tracker mounted to said retractor.
7. A retractor for placement of a pedicle screw, comprising:
 - a guide portion including a guide channel;
 - 25 an insert configured to fit within said guide channel, said insert having a hollow bore extending lengthwise therethrough, said bore having a diameter sized to accommodate a tool inserted therethrough; and
 - means for stabilizing said insert within said guide channel.
8. The device as claimed in claim 7, wherein said guide channel includes a distal end, said distal end having at least one projection extending therefrom.
- 30 9. The device as claimed in claim 7, wherein said guide portion includes a medial face positioned adjacent said second end thereof, said medial face having a medial service formed with texturing thereon.

10. The device as claimed in claim 7, further comprising an image tracker mounted to said retractor.

11. A surgical retractor for guiding implantation of a pedicle screw within a patient's spine, comprising:

5 a guide portion having a guide channel, said guide channel sized to accommodate a pedicle screw for implanting in the patient, said guide portion having a distal end; and means for stabilizing the distal end of said guide portion against a lateral aspect of a facet of a paraspinal musculature of the patient.

12. The device as claimed in claim 11, further comprising an elongated insert 10 configured to fit within said guide channel, said insert having an aperture extending lengthwise therethrough.

13. The device as claimed in claim 12, further comprising grooves formed on said guide channel for receiving at least one base edge of said insert.

14. The device as claimed in claim 11, further comprising an image tracker 15 mounted to said retractor.

15. The device as claimed in claim 11, further comprising a semi-circular opening sized to accommodate a pedicle screw at said distal end of said guide portion.

16. In combination, a retractor especially adapted for spinal surgery and an image tracker, said combination comprising:

20 a retractor having a guide portion and a guide channel portion extending longitudinally therewith;

a handle connected to said guide portion; and

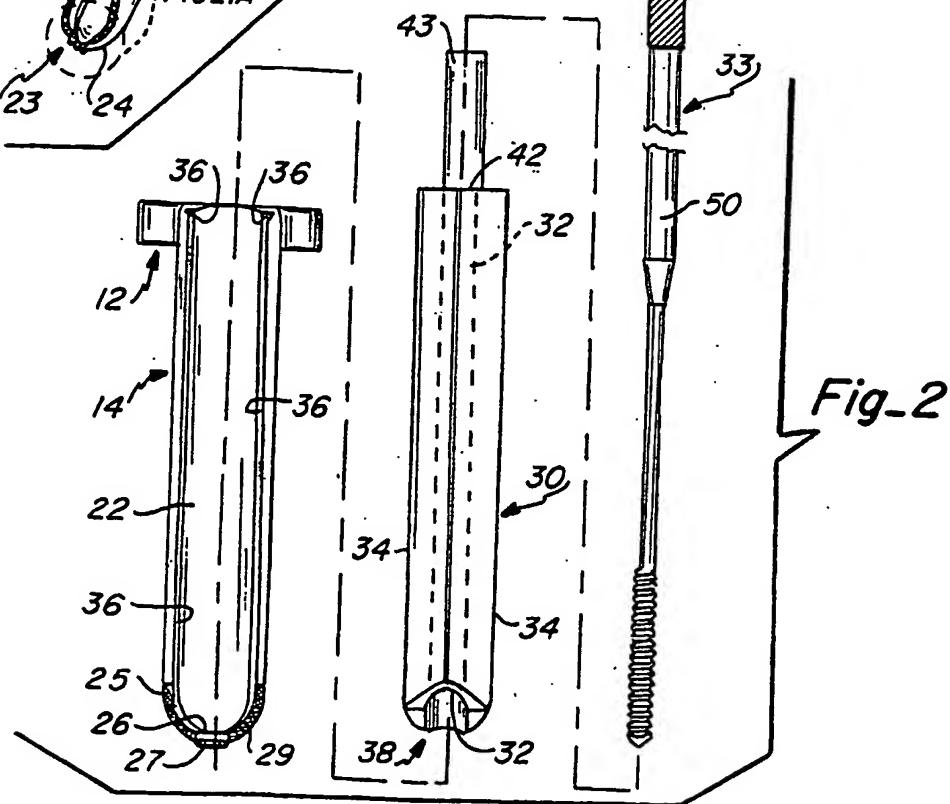
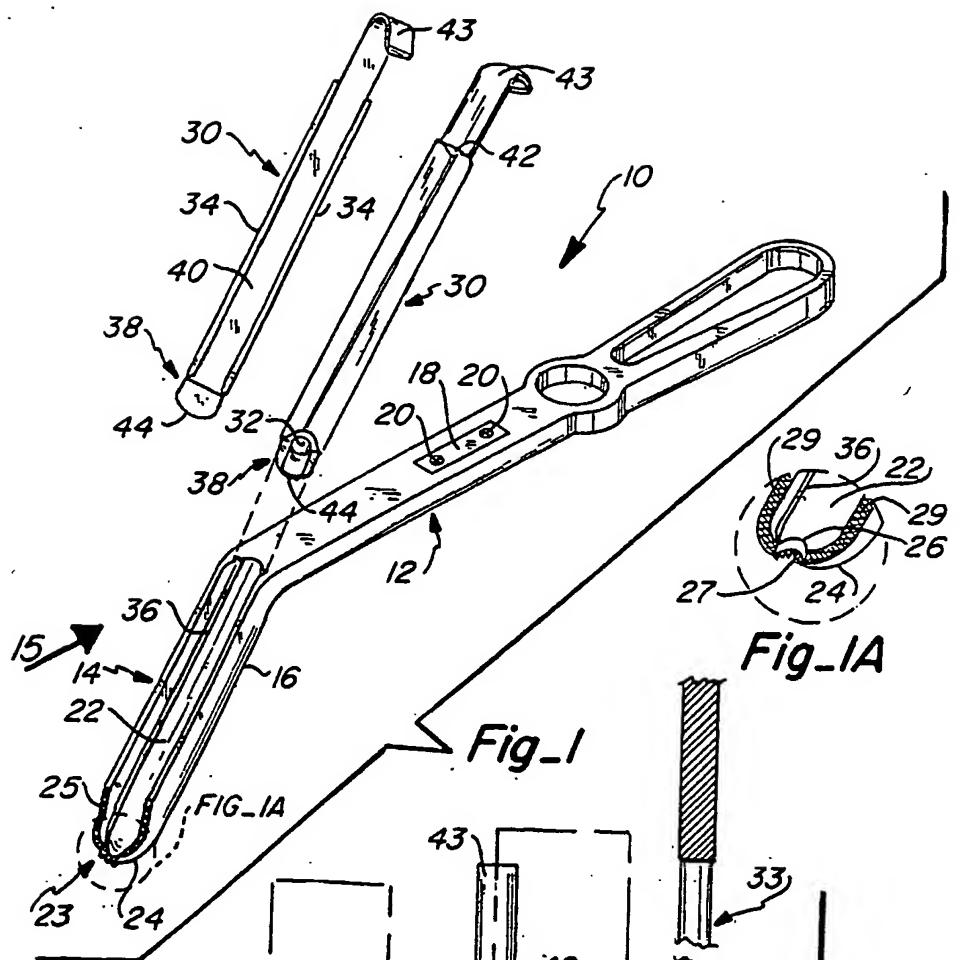
an image tracker connected to said handle, wherein the image tracker allows the guide channel to be aligned on the surgical site.

25 17. The combination as claimed in claim 16, further comprising an insert configured to fit within said guide channel, said insert having an aperture extending lengthwise therethrough, said aperture having a diameter sized to accommodate a tool inserted therethrough.

18. The combination as claimed in claim 17, wherein said tool is a tap.

30 19. The combination as claimed in claim 18, wherein said insert includes a proximal opening sized to prevent a larger diameter section of said tap from passing into said aperture.

20. A method for placing a pedicle screw, comprising:
- providing a retractor including a guide portion having first and second ends, said guide portion including a guide channel, said guide portion having a handle operatively connected thereto;
- 5 placing said guide portion so as to extend from a skin surface of a patient to a dorsal aspect of a vertebra over a pedicle of said patient;
- manipulating said handle so as to maintain a position of said guide portion against a lateral aspect of a facet of a paraspinous musculature of said patient;
- inserting an insert into said channel of said retractor, said insert having a hollow bore
- 10 sized to accommodate a tool selected from the group consisting of a drill bit, a tap for a pedicle and a probe;
- utilizing the tool to complete a desired surgical step within a surgical procedure;
- removing said insert after utilizing said tool; and
- inserting a pedicle screw into said pedicle.



2/3

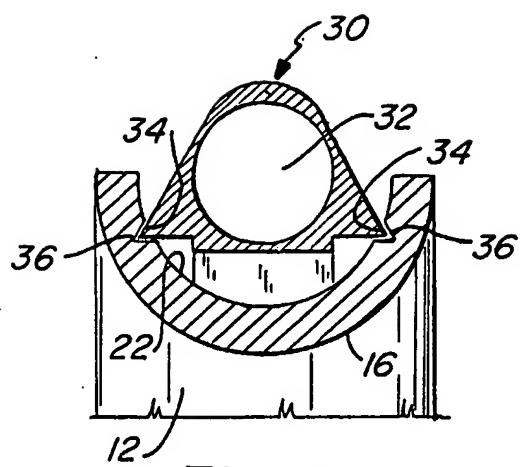


Fig. 4

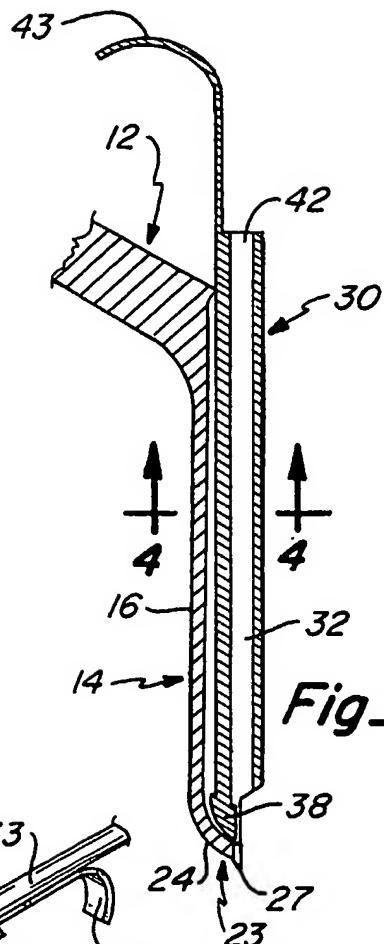
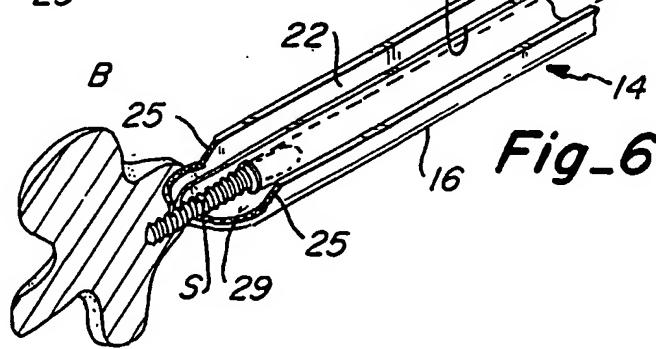
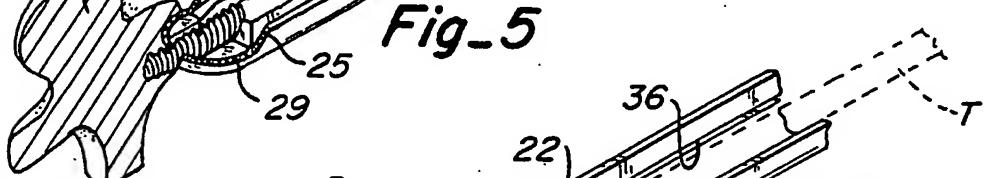
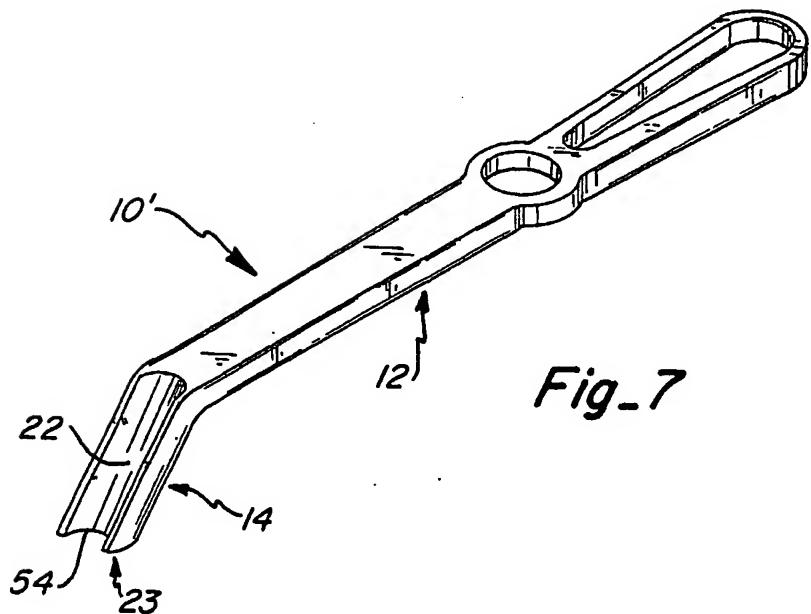
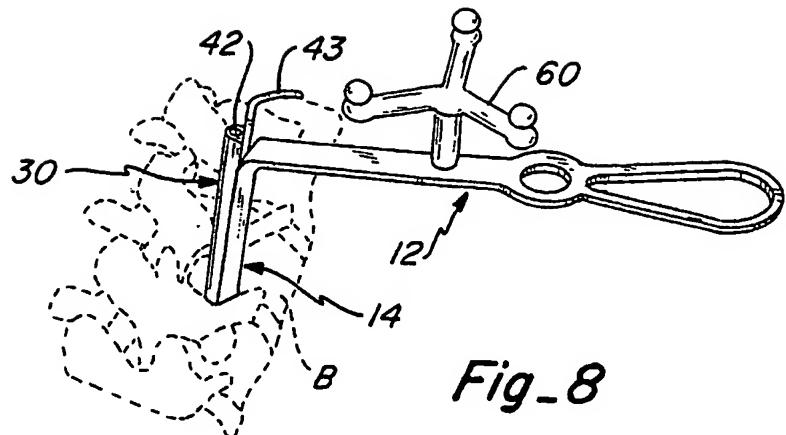


Fig. 3



Fig. 5





INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/02703

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/58

US CL : 606/104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/104,74,80,88,232,96,99; 623/13.11,17.11,17.16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

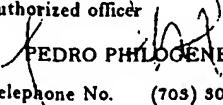
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,766,221A (Benderev et al) 16 June 1998, see entire document	1-4,20
A,P	US 6,206,885 B1 (Ghahremani et al) 27 March 2001, see entire document	1-20
A	US 5,601,550 A (Esser) 11 February 1997, see entire document	1-20
A	US 5,895,390 A (Moran et al.) 20 April 1999, see entire document	1-20
A	US 5,885,300 A (Tokuhashi et al.) 23 March 1999, see entire document	1-20
A	US 4,617,922 A (Griggs) 21 October 1986, see entire document	1-20

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
25 APRIL 2002	01 JUL 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  PEDRO PHILOCENE
Facsimile No. (703) 305-3230	Telephone No. (703) 308-8252

THIS PAGE BLANK (USPTO)